CASE D0028 NP

CERTIFICATE OF MAILING

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Audrey F. Sher	Audrey F. Sher	October 21, 2005
Type or print name	Signature	Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF
Robert J. Peach, et al.
APPLICATION NO: 09/865,321
FILED: May 23, 2001
FOR: SOLUBLE CTLA4 MUTANT MOLECULES AND USES THEREOF

Art Unit: 1646
Examiner: Ilia Ouspenski

Mail Stop **RCE**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

This Information Disclosure Statement is submitted under 37 C.F.R. §1.97(b).

In accordance with 37 C.F.R. §1.56, Applicants wish to call the Examiner's attention to the information listed both below and on the attached form(s) PTO-1449, including the attached Exhibits. In accordance with 37 C.F.R. §1.56, Applicants do not include below information which Applicants believe cumulative of information already of record or herein being made of record in the application.

In the information listed below, "physical sample" refers to an actual physical sample rather than information describing a physical sample. "Nucleic acid sequence encoding a molecule" and "amino acid sequence of a molecule" refer to sequence information, rather than a physical sample of a molecule. "The earliest priority date of the subject application" refers to May 26, 2000.

Various redacted copies of documents are provided as exhibits hereto. Applicants invite the Examiner to request an unredacted copy of any exhibited document if necessary. Applicants invite

the Examiner to request additional information concerning the information provided herein if necessary.

1. Bristol-Myers Squibb Company provided a physical sample of a molecule covered by at least one claim of the subject application (hereinafter "claimed molecule") to Emory University less than one year before the earliest priority date of the subject application for use in animal studies in the U.S. The Information Disclosure Statement dated November 4, 2002 states that: "L104EA29Y (Figure 7, of the subject application) was provided to researchers at Emory University, subject to use restrictions and confidentiality by agreement, more than one year before the priority date of the subject application, i.e. May 26, 2000, for use in animal studies in the U.S.." That statement was made in error. L104EA29Y, which is a claimed molecule, was provided to Emory University, subject to use restrictions and confidentiality by agreement, less than one year before the earliest priority date of the subject application, for use in animal studies in the U.S. Attached hereto as **Exhibit 195** is a redacted copy of a written agreement, including use restrictions and provisions for confidentiality, between Bristol-Myers Squibb Company and Emory University.

2. Bristol-Myers Squibb Company provided a physical sample of nucleic acid molecule encoding a claimed molecule to Genzyme Transgenics Corporation, subject to use restrictions and confidentiality by agreement, more than one year before the earliest priority date of the subject application. Bristol-Myers Squibb Company may have provided a nucleic acid sequence encoding a claimed molecule to Genzyme Transgenics Corporation, subject to use restrictions and confidentiality by agreement, more than one year before the earliest priority date of the subject application. The Examiner should assume that a nucleic acid sequence encoding a claimed molecule was provided to Genzyme Transgenics Corporation, subject to use restrictions and confidentiality by agreement, more than one year before the earliest priority date of the subject application. Bristol-Myers Squibb Company engaged Genzyme Transgenics Corporation to make transgenic animals that produced a claimed molecule. Attached hereto as **Exhibits 196 - 198** are redacted copies of three written agreements, including use restrictions and provisions for confidentiality, between Bristol-Myers Squibb Company and Genzyme Transgenics Corporation.

3. Bristol-Myers Squibb Company provided a physical sample of a claimed molecule to Applied Analytical Industries, Inc., subject to use restrictions and confidentiality by agreement, before the earliest priority date of the subject application. Bristol-Myers Squibb Company provided the physical sample while considering doing analytical method transfer to Applied Analytical Industries, Inc. Attached hereto as **Exhibit 199** is a redacted copy of a written agreement, including use

restrictions and provisions for confidentiality, between Bristol-Myers Squibb Company and Applied Analytical Industries, Inc.

4. Bristol-Myers Squibb Company provided a physical sample of a claimed molecule to Tektagen, Inc., subject to use restrictions and confidentiality by agreement, more than a year before the earliest priority date of the subject application. Bristol-Myers Squibb Company engaged Tektagen, Inc. on a fee for service basis to test for residual CHO cell DNA in the physical sample. Attached hereto as **Exhibit 200** is a redacted copy of a written agreement, including use restrictions and provisions for confidentiality, between Bristol-Myers Squibb Company and Tektagen, Inc.

5. Bristol-Myers Squibb Company provided a physical sample of a claimed molecule to Northview Pacific Laboratories Inc. more than a year before the earliest priority date of the subject application. Bristol-Myers Squibb Company engaged Northview Pacific Laboratories Inc. on a fee for service basis to test for pyrogens in the physical sample. The undersigned attorney is not aware of an agreement including use restrictions and provisions for confidentiality concerning this provision of a claimed molecule to Northview Pacific Laboratories Inc..

6. Bristol-Myers Squibb Company provided a physical sample of cells containing nucleic acid encoding a claimed molecule to MA BioServices, Inc. more than a year before the earliest priority date of the subject application. Bristol-Myers Squibb Company engaged MA BioServices, Inc., later known as BioReliance Corp., on a fee for service basis to test for viral contaminants in the physical sample. The undersigned attorney is not aware of an agreement including use restrictions and provisions for confidentiality concerning this provision of cells containing nucleic acid encoding a claimed molecule to MA BioServices, Inc.

7. Bristol-Myers Squibb Company provided a physical sample of cell culture broth containing a claimed molecule to Advanced Biotechnologies Inc. more than a year before the earliest priority date of the subject application. Bristol-Myers Squibb Company engaged Advanced Biotechnologies Inc. on a fee for service basis to test for viral contaminants in the physical sample. The undersigned attorney is not aware of an agreement including use restrictions and provisions for confidentiality concerning this provision of cell culture broth containing a claimed molecule to Advanced Biotechnologies Inc.

8. Bristol-Myers Squibb Company provided a physical sample of a claimed molecule to Quality Biotech Inc. more than a year before the earliest priority date of the subject application. Bristol-Myers Squibb Company engaged Quality Biotech Inc., later known as AppTec Inc., on a fee for

service basis to test for viral contaminants in the physical sample. The undersigned attorney is not aware of an agreement including use restrictions and provisions for confidentiality concerning this provision of a claimed molecule to Quality Biotech Inc.

9. Bristol-Myers Squibb Company provided physical samples of a claimed molecule to certain parties involved in human clinical trials in the United States before the earliest priority date of the subject application, some more than one year before the earliest priority date of the subject application. Bristol-Myers Squibb provided physical samples of a claimed molecule to certain parties involved in human clinical trials outside the United States before the earliest priority date of the subject application, some more than one year before the earliest priority date of the subject application. Attached hereto as **Exhibits 201 - 242** are redacted copies of written agreements, including use restrictions and provisions for confidentiality, between Bristol-Myers Squibb Company and these parties in the United States to whom Bristol-Myers Squibb Company provided a physical sample of a claimed molecule at any time before the earliest priority date of the subject application. In the human clinical trials, the claimed molecule was administered intravenously to human patients. As explained in the Information Disclosure Statement dated November 4, 2002, a claimed molecule was first administered intravenously to a human patient as early as November 30, 1998 in Scottland, U.K., and a claimed molecule was first administered intravenously to a human patient as early as April 24, 1999 in the United States.

10. As explained in the Information Disclosure Statement dated November 4, 2002, Bristol-Myers Squibb Company provided, pursuant to applicable regulations concerning confidentiality, the amino acid sequence of a claimed molecule to the U.S. Food and Drug Administration in a letter dated July 9,1998 including a report. Bristol-Myers Squibb Company also provided, pursuant to applicable regulations concerning confidentiality, an amino acid sequence of a claimed molecule to the U.S. Food and Drug Administration in an Investigational New Drug Application more than one year before the earliest priority date of the subject application.

11. In 1999 more than one year before the earliest priority date of the subject application, Bristol-Myers Squibb Company provided the amino acid sequence of a claimed molecule to regulatory agencies in Canada, the United Kingdom, Ireland, France, Belgium, and possibly Switzerland, in relation to human clinical trials to be conducted in those countries. The Examiner should assume that the amino acid sequence of a claimed molecule was provided to a regulatory agency in Switzerland more than one year before the earliest priority date of the subject application. The regulatory agencies that received the amino acid sequence of a claimed molecule either have

to keep the information confidential pursuant to applicable law, or have an agency practice of treating the information as confidential. The Examiner is invited to investigate the laws pertaining to and practices of these regulatory agencies.

12. Bristol-Myers Squibb Company provided clinical trial protocols dated October 20, 1998 revised November 17, 1998, January 25, 1999, and January 25, 1999 revised April 8, 1999 to certain parties involved in human clinical trials more than one year before the earliest priority date of the subject application. Attached hereto as **Exhibits 243 - 245** are redacted copies of these clinical trial protocols. Descriptions of the molecule used in the clinical trials can be found on pages 9 and 13 of the redacted October 20, 1998 revised November 17, 1998 protocol, on pages 12 and 17 of the redacted January 25, 1999 protocol, and on pages 12 and 17 of the redacted January 25, 1999 revised April 8, 1999 protocol. Although Exhibits 243 - 245 are labeled confidential, Applicants at this time do not assert that Bristol-Myers Squibb Company provided these documents to the recipients subject to an obligation of confidentiality or that the recipients treated the documents as confidential. Applicants may in the future establish that Bristol-Myers Squibb Company provided these documents to the recipients subject to an obligation of confidentiality or that these documents were treated as confidential by the recipients. For purposes of this Information Disclosure Statement, the Examiner should not consider these documents to have been provided to the recipients subject to an obligation of confidentiality, and should not consider these documents to have been treated as confidential by the recipients.

13. Bristol-Myers Squibb Company provided Investigator Brochures to certain parties involved in human clinical trials before the earliest priority date of the subject application. An Investigator Brochure dated January 26, 1999, a redacted copy of which was submitted as Exhibit 172 with the Information Disclosure Statement dated November 4, 2002, was provided to certain parties involved in human clinical trials more than one year before the earliest priority date of the subject application. Description of the molecule used in the clinical trials can be found on page 6 of the redacted January 26, 1999 Investigator Brochure. Attached as **Exhibit 246** is a redacted copy of an Investigator Brochure dated October 23, 1998. This October 23, 1998 Investigator Brochure was provided to certain parties involved in human clinical trials more than one year before the earliest priority date of the subject application. Description of the molecule used in the clinical trials can be found on page 7 of the redacted October 23, 1998 Investigator Brochure. Attached as **Exhibit 247** is a redacted copy of an Investigator Brochure dated May 10, 2000. This May 10, 2000 Investigator Brochure may have been provided to certain parties involved in human clinical trials before the earliest priority date of the subject application. Description of the molecule used in the clinical trials

can be found on page 7 of the redacted May 10, 2000 Investigator Brochure. The Examiner should assume that the May 10, 2000 Investigator Brochure was provided to certain parties involved in human clinical trials before the earliest priority date of the subject application. Although Exhibits 172, 246 and 247 are labeled confidential, Applicants at this time do not assert that Bristol-Myers Squibb Company provided these documents to the recipients subject to an obligation of confidentiality or that the recipients treated the documents as confidential. Applicants may in the future establish that Bristol-Myers Squibb Company provided these documents to the recipients subject to an obligation of confidentiality or that these documents were treated as confidential by the recipients. For purposes of this Information Disclosure Statement, the Examiner should not consider these documents to have been provided to the recipients subject to an obligation of confidentiality, and should not consider these documents to have been treated as confidential by the recipients.

No representation is made that any information or document provided herein is prior art within the meaning of 35 U.S.C. § 102 or 103, and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish that information or a document is not prior art.

The Examiner is requested to consider the foregoing information in relation to this application and indicate that each item of information was considered by returning a copy of the initialed PTO 1449 form(s). Applicants request that the information listed on the attached PTO 1449 form not be printed on the face of a patent. Applicants have used the PTO 1449 form(s) to provide a convenient way for the Examiner to indicate his consideration of the listed information.

Respectfully submitted,

Audrey F. Sher
Attorney for Applicants
Reg. No. 39,024

Bristol-Myers Squibb Company
Patent Department
P.O. Box 4000
Princeton, NJ 08543-4000
(609) 252-3218

Date: October 21, 2005

PTO/SB/08B (8/03)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT(S)

(use as many sheets as necessary)

Sheet	1	of	5

COMPLETE IF KNOWN	
Application Number	09/865,321
Filing Date	05/23/2001
First Named Inventor	ROBERT PEACH
Art Unit	1644
Examiner Name	OUSPENSKI, ILIA
Attorney Docket Number	D0028 NP

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article(when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	Check box if English language Translation is attached
		Bristol-Myers Squibb Company provided a physical sample of a molecule covered by at least one claim of the subject application (hereinafter "claimed molecule") to Emory University less than one year before the earliest priority date of the subject application for use in animal studies in the U.S. The Information Disclosure Statement dated November 4, 2002 states that: "L104EA29Y (Figure 7, of the subject application) was provided to researchers at Emory University, subject to use restrictions and confidentiality by agreement, more than one year before the priority date of the subject application, i.e. May 26, 2000, for use in animal studies in the U.S.." That statement was made in error. L104EA29Y, which is a claimed molecule, was provided to Emory University, subject to use restrictions and confidentiality by agreement, less than one year before the earliest priority date of the subject application, for use in animal studies in the U.S. Attached hereto as **Exhibit 195** is a redacted copy of a written agreement, including use restrictions and provisions for confidentiality, between Bristol-Myers Squibb Company and Emory University.	
		Exhibit 195 – Research Agreement between Bristol-Myers Squibb Company and Emory University	
		Bristol-Myers Squibb Company provided a physical sample of nucleic acid molecule encoding a claimed molecule to Genzyme Transgenics Corporation, subject to use restrictions and confidentiality by agreement, more than one year before the earliest priority date of the subject application. Bristol-Myers Squibb Company may have provided a nucleic acid sequence encoding a claimed molecule to Genzyme Transgenics Corporation, subject to use restrictions and confidentiality by agreement, more than one year before the earliest priority date of the subject application. The Examiner should assume that a nucleic acid sequence encoding a claimed molecule was provided to Genzyme Transgenics Corporation, subject to use restrictions and confidentiality by agreement, more than one year before the earliest priority date of the subject application. Bristol-Myers Squibb Company engaged Genzyme Transgenics Corporation to make transgenic animals that produced a claimed molecule. Attached hereto as **Exhibits 196 - 198** are redacted copies of three written agreements, including use restrictions and provisions for confidentiality, between Bristol-Myers Squibb Company and Genzyme Transgenics Corporation	
		Exhibit 196 – Material Transfer Agreement between Bristol-Myers Squibb Company and Genzyme Transgenics Corporation	
		Exhibit 197 – Confidential Disclosure Agreement between Bristol-Myers Squibb Company and Genzyme Transgenics Corporation	
		Exhibit 198 – Agreement for the Generation of Founder Goats between Bristol-Myers Squibb Company and Genzyme Transgenics Corporation	
		Bristol-Myers Squibb Company provided a physical sample of a claimed molecule to Applied Analytical Industries, Inc., subject to use restrictions and confidentiality by agreement, before the earliest priority date of the subject application. Bristol-Myers Squibb Company provided the physical sample while considering doing analytical method transfer to Applied Analytical Industries, Inc. Attached hereto as **Exhibit 199** is a redacted copy of a written agreement, including use restrictions and provisions for confidentiality, between Bristol-Myers Squibb Company and Applied Analytical Industries, Inc.	
		Exhibit 199 – Confidential Disclosure Agreement between Bristol-Myers Squibb Co. and Applied Analytical Industries, Inc.	
		Bristol-Myers Squibb Company provided a physical sample of a claimed molecule to Tektagen, Inc., subject to use restrictions and confidentiality by agreement, more than a year before the earliest priority date of the subject application. Bristol-Myers Squibb Company engaged Tektagen, Inc. on a fee for service basis to test for residual CHO cell DNA in the physical sample. Attached hereto as **Exhibit 200** is a redacted copy of a written agreement, including use restrictions and provisions for confidentiality, between Bristol-Myers Squibb Company and Tektagen, Inc.	
		Exhibit 200 – Confidential Disclosure Agreement between Bristol-Myers Squibb Company and Tektagen, Inc.	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant

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COMPLETE IF KNOWN	
Application Number	09/865,321
Filing Date	05/23/2001
First Named Inventor	ROBERT PEACH
Art Unit	1644
Examiner Name	OUSPENSKI, ILIA
Attorney Docket Number	D0028 NP

Sheet 2 of 5

		Bristol-Myers Squibb Company provided a physical sample of a claimed molecule to Northview Pacific Laboratories Inc. more than a year before the earliest priority date of the subject application. Bristol-Myers Squibb Company engaged Northview Pacific Laboratories Inc. on a fee for service basis to test for pyrogens in the physical sample. The undersigned attorney is not aware of an agreement including use restrictions and provisions for confidentiality concerning this provision of a claimed molecule to Northview Pacific Laboratories Inc..	
		Bristol-Myers Squibb Company provided a physical sample of cells containing nucleic acid encoding a claimed molecule to MA BioServices, Inc. more than a year before the earliest priority date of the subject application. Bristol-Myers Squibb Company engaged MA BioServices, Inc., later known as BioReliance Corp., on a fee for service basis to test for viral contaminants in the physical sample. The undersigned attorney is not aware of an agreement including use restrictions and provisions for confidentiality concerning this provision of cells containing nucleic acid encoding a claimed molecule to MA BioServices, Inc.	
		Bristol-Myers Squibb Company provided a physical sample of cell culture broth containing a claimed molecule to Advanced Biotechnologies Inc. more than a year before the earliest priority date of the subject application. Bristol-Myers Squibb Company engaged Advanced Biotechnologies Inc. on a fee for service basis to test for viral contaminants in the physical sample. The undersigned attorney is not aware of an agreement including use restrictions and provisions for confidentiality concerning this provision of cell culture broth containing a claimed molecule to Advanced Biotechnologies Inc.	
		Bristol-Myers Squibb Company provided a physical sample of a claimed molecule to Quality Biotech Inc. more than a year before the earliest priority date of the subject application. Bristol-Myers Squibb Company engaged Quality Biotech Inc., later known as AppTec Inc., on a fee for service basis to test for viral contaminants in the physical sample. The undersigned attorney is not aware of an agreement including use restrictions and provisions for confidentiality concerning this provision of a claimed molecule to Quality Biotech Inc.	
		Bristol-Myers Squibb Company provided physical samples of a claimed molecule to certain parties involved in human clinical trials in the United States before the earliest priority date of the subject application, some more than one year before the earliest priority date of the subject application. Bristol-Myers Squibb provided physical samples of a claimed molecule to certain parties involved in human clinical trials outside the United States before the earliest priority date of the subject application, some more than one year before the earliest priority date of the subject application. Attached hereto as **Exhibits 201 - 242** are redacted copies of written agreements, including use restrictions and provisions for confidentiality, between Bristol-Myers Squibb Company and these parties in the United States to whom Bristol-Myers Squibb Company provided a physical sample of a claimed molecule at any time before the earliest priority date of the subject application. In the human clinical trials, the claimed molecule was administered intravenously to human patients. As explained in the Information Disclosure Statement dated November 4, 2002, a claimed molecule was first administered intravenously to a human patient as early as November 30, 1998 in Scottland, U.K., and a claimed molecule was first administered intravenously to a human patient as early as April 24, 1999 in the United States.	
		Exhibit 201 – Confidential Disclosure Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial.	
		Exhibit 202 – Clinical Trial Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial.	
		Exhibit 203 – Confidential Disclosure Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial	
		Exhibit 204 – Clinical Trial Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial.	
		Exhibit 205 – Confidential Disclosure Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial	
		Exhibit 206 – Clinical Trial Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial.	
		Exhibit 207 – Confidential Disclosure Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial	
		Exhibit 208 – Clinical Trial Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial.	
		Exhibit 209 – Confidential Disclosure Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial	

Examiner Signature		Date Considered	

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Sheet 3 of 5

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Filing Date	05/23/2001
First Named Inventor	ROBERT PEACH
Art Unit	1644
Examiner Name	OUSPENSKI, ILIA
Attorney Docket Number	D0028 NP

		Exhibit 210 – Clinical Trial Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial.	
		Exhibit 211 – Confidential Disclosure Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial	
		Exhibit 212 – Clinical Trial Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial.	
		Exhibit 213 – Confidential Disclosure Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial	
		Exhibit 214 – Clinical Trial Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial.	
		Exhibit 215 – Confidential Disclosure Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial	
		Exhibit 216 – Clinical Trial Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial.	
		Exhibit 217 – Confidential Disclosure Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial	
		Exhibit 218 – Clinical Trial Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial.	
		Exhibit 219 – Confidential Disclosure Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial	
		Exhibit 220 – Clinical Trial Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial.	
		Exhibit 221 – Confidential Disclosure Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial	
		Exhibit 222 – Clinical Trial Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial.	
		Exhibit 223 – Confidential Disclosure Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial	
		Exhibit 224 – Clinical Trial Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial.	
		Exhibit 225 – Confidential Disclosure Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial	
		Exhibit 226 – Clinical Trial Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial.	
		Exhibit 227 – Confidential Disclosure Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial	
		Exhibit 228 – Clinical Trial Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial.	
		Exhibit 229 – Confidential Disclosure Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial	
		Exhibit 230 – Clinical Trial Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial.	
		Exhibit 231 – Confidential Disclosure Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial	
		Exhibit 232 – Clinical Trial Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial.	
		Exhibit 233 – Confidential Disclosure Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial	
		Exhibit 234 – Clinical Trial Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial.	
		Exhibit 235 – Confidential Disclosure Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial	

Examiner Signature		Date Considered	

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Examiner Name	OUSPENSKI, ILIA
Attorney Docket Number	D0028 NP

Sheet 4 of 5

		Exhibit 236 – Clinical Trial Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial.	
		Exhibit 237 – Confidential Disclosure Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial	
		Exhibit 238 – Clinical Trial Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial.	
		Exhibit 239 – Confidential Disclosure Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial	
		Exhibit 240 – Clinical Trial Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial.	
		Exhibit 241 – Confidential Disclosure Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial	
		Exhibit 242 – Clinical Trial Agreement between Bristol-Myers Squibb Company and a party involved in a human clinical trial.	
		As explained in the Information Disclosure Statement dated November 4, 2002, Bristol-Myers Squibb Company provided, pursuant to applicable regulations concerning confidentiality, the amino acid sequence of a claimed molecule to the U.S. Food and Drug Administration in a letter dated July 9,1998 including a report. Bristol-Myers Squibb Company also provided, pursuant to applicable regulations concerning confidentiality, an amino acid sequence of a claimed molecule to the U.S. Food and Drug Administration in an Investigational New Drug Application more than one year before the earliest priority date of the subject application.	
		In 1999 more than one year before the earliest priority date of the subject application, Bristol-Myers Squibb Company provided the amino acid sequence of a claimed molecule to regulatory agencies in Canada, the United Kingdom, Ireland, France, Belgium, and possibly Switzerland, in relation to human clinical trials to be conducted in those countries. The Examiner should assume that the amino acid sequence of a claimed molecule was provided to a regulatory agency in Switzerland more than one year before the earliest priority date of the subject application. The regulatory agencies that received the amino acid sequence of a claimed molecule either have to keep the information confidential pursuant to applicable law, or have an agency practice of treating the information as confidential. The Examiner is invited to investigate the laws pertaining to and practices of these regulatory agencies.	
		Bristol-Myers Squibb Company provided clinical trial protocols dated October 20, 1998 revised November 17, 1998, January 25, 1999, and January 25, 1999 revised April 8, 1999 to certain parties involved in human clinical trials more than one year before the earliest priority date of the subject application. Attached hereto as **Exhibits 243 - 245** are redacted copies of these clinical trial protocols. Descriptions of the molecules used in the clinical trials can be found on pages 9 and 13 of the redacted October 20, 1998 revised November 17, 1998 protocol, on pages 12 and 17 of the redacted January 25, 1999 protocol, and on pages 12 and 17 of the redacted January 25, 1999 revised April 8, 1999 protocol. Although Exhibits 243 - 245 are labeled confidential, Applicants at this time do not assert that Bristol-Myers Squibb Company provided these documents to the recipients subject to an obligation of confidentiality or that the recipients treated the documents as confidential. Applicants may in the future establish that Bristol-Myers Squibb Company provided these documents to the recipients subject to an obligation of confidentiality or that these documents were treated as confidential by the recipients. For purposes of this Information Disclosure Statement, the Examiner should not consider these documents to have been provided to the recipients subject to an obligation of confidentiality, and should not consider these documents to have been treated as confidential by the recipients.	
		Exhibit 243 – Clinical Trial Protocol dated October 20, 1998 revised November 17, 1998	
		Exhibit 244 – Clinical Trial Protocol dated January 25, 1999	
		Exhibit 245 – Clinical Trial Protocol dated January 25, 1999 revised April 8, 1999	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant

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Examiner Name	OUSPENSKI, ILIA
Attorney Docket Number	D0028 NP

		Bristol-Myers Squibb Company provided Investigator Brochures to certain parties involved in human clinical trials before the earliest priority date of the subject application. An Investigator Brochure dated January 26, 1999, a redacted copy of which was submitted as Exhibit 172 with the Information Disclosure Statement dated November 4, 2002, was provided to certain parties involved in human clinical trials more than one year before the earliest priority date of the subject application. Description of the molecule used in the clinical trials can be found on page 6 of the redacted January 26, 1999 Investigator Brochure. Attached as **Exhibit 246** is a redacted copy of an Investigator Brochure dated October 23, 1998. This October 23, 1998 Investigator Brochure was provided to certain parties involved in human clinical trials more than one year before the earliest priority date of the subject application. Description of the molecule used in the clinical trials can be found on page 7 of the redacted October 23, 1998 Investigator Brochure. Attached as **Exhibit 247** is a redacted copy of an Investigator Brochure dated May 10, 2000. This May 10, 2000 Investigator Brochure may have been provided to certain parties involved in human clinical trials before the earliest priority date of the subject application. Description of the molecule used in the clinical trials can be found on page 7 of the redacted May 10, 2000 Investigator Brochure. The Examiner should assume that the May 10, 2000 Investigator Brochure was provided to certain parties involved in human clinical trials before the earliest priority date of the subject application. Although Exhibits 172, 246 and 247 are labeled confidential, Applicants at this time do not assert that Bristol-Myers Squibb Company provided these documents to the recipients subject to an obligation of confidentiality or that the recipients treated the documents as confidential. Applicants may in the future establish that Bristol-Myers Squibb Company provided these documents to the recipients subject to an obligation of confidentiality or that these documents were treated as confidential by the recipients. For purposes of this Information Disclosure Statement, the Examiner should not consider these documents to have been provided to the recipients subject to an obligation of confidentiality, and should not consider these documents to have been treated as confidential by the recipients.	
		Exhibit 246 – Investigator Brochure dated October 23, 1998	
		Exhibit 247 – Investigator Brochure dated May 10, 2000	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant